K070524

Summary for Public Disclosure

JUN 22 2007

Applicant:	Cambridge Sensors Ltd. Units 9 and 10, Cardinal Park, Godmanchester, Huntingdon, Cambridgeshire, PE29 2XG United Kingdom
Contact:	Dr. Bernadette Yon-Hin
Date Summary Prepared:	9th January 2007
Device Trade Name:	microdot® Blood Glucose Monitoring System
Common Name:	Self Monitoring Blood Glucose Test
Classification Name:	Whole blood glucose test
Equivalent Device:	LifeScan Ultra Blood Glucose System
Device Description:	The microdot® Blood Glucose System is comprised of the microdot® Meter, Test Strips, & three controls. The test strip is inserted into the device, a drop of blood is added to the strip, and a glucose result is presented in 10 seconds. The test principle is based on electrochemical biosensor technology. Glucose dehydrogenase converts to glucose to gluconolactone, with reduction of NAD to NADH. Re-oxidation of the mediator by the meter induces a micro current to flow, and the size of the micro current is directly proportional to the amount of glucose in the blood. The micro current is detected in of the blood glucose concentration.
Intended use:	The microdot® Blood Glucose Monitoring System is intended to measure glucose in whole capillary blood by persons with diabetes or by health care professionals in the home or in health care facilities.

Comparison to Predicate:	The microdot® Blood Glucose Monitoring System is substantially equivalent to the LifeScan One Touch Ultra blood glucose testing system.
Non-Clinical performance:	Linearity studies with venous blood spiked with glucose from 20 to 520 mg/dL gave a slope of 0.93 and 0.94 respectively with 2 lots of strips and a correlation coefficient of 0.996. Within run precision of 20 readings with glucose spiked venous blood carried out in one day gave cv's of 5.48 % at 43 mg/dL, 4.01% at 81 mg/dL, 3.31% at 124 mg/dl and 2.91% at 197 mg/dL and 2.9% at 296 mg/dL. Effect of hematocrit over the range of 30 to 50% was tested at nominal glucose concentrations of 60, 150, 250 and 400 mg/dL. There is a positive bias at low hematocrit and a negative bias at high hematocrit. The results shown that in the range 30– 50%, the bias criteria of ≤± 15 mg/dL for samples below 75 mg/dL and ≤±20% for samples above 75 mg/dL is met.
Clinical Study:	In a clinical study carried out with 121 diabetic patients, the regression equation for microdot® against the YSI reference method was y=1.0055x + 0.7776, r = 0.982 when the tests were carried out by healthcare professionals. Te same patient samples tested on the One Touch® Ultra™ by healthcare professionals gave a linear regression equation of y = 0.9705 - 1.3727, r = 0.988.
Conclusion:	The microdot® Blood Glucose Test System is substantially equivalent to the LifeScan One Touch Ultra blood glucose monitor.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Cambridge Sensor Limited
c/o Mr. Warren Reeves
Units 9 and 10, Cardinal Park
Godmanchester, Huntingdon
Cambridgeshire PE29 2XG
United Kingdom

JUN 22 2007

Re: k070524
Trade Name: Microdot Blood Glucose Monitoring System
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose Test System
Regulatory Class: Class II
Product Code: 75, NBW, LFR, JJX
Dated: May 24, 2007
Received: May 31, 2007

Dear Mr. Reeves:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0490. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address at http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Jean M. Cooper, M.S., D.V.M.

Jean M. Cooper, M.S., D.V.M.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): k070524

Device Name: Microdot Blood Glucose Monitoring System: blood glucose monitor

Indications For Use:
microdot Blood Glucose Monitoring System
The microdot Blood Glucose Monitoring System is intended for self testing of glucose in capillary whole blood by persons with diabetes or by health care professionals in home settings or healthcare facilities. It is intended for monitoring of blood glucose levels only.

microdot Blood Glucose Meter
The microdot Blood Glucose Meter is intended for the quantitative measurement of glucose in fresh capillary whole blood from a fingerstick. It is intended for use by persons with diabetes or by health care professionals in home settings or healthcare facilities. It is intended for monitoring of blood glucose levels only.

microdot Test Strips
The microdot Test Strips are intended for the quantitative measurement of glucose in fresh capillary whole blood from a fingerstick. It is intended for use by persons with diabetes or by health care professionals in home settings or healthcare facilities. It is intended for monitoring of blood glucose levels only.

microdot Control solutions
The microdot Control solutions are intended for use with microdot Blood Glucose Meter and microdot Test Strips as a quality control check to verify the accuracy of the blood glucose test results.

Prescription Use _____ AND/OR Over-The-Counter Use X
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) k070524